

Appl. No. 10/037,526
Amdt. dated Nov. 18, 2003
Reply to Office Action of June 18, 2003

REMARKS/ARGUMENTS

Claim 1 has been amended in order to include jojoba oil and borage oil as two ingredients which are included in the composition. This amendment does not constitute new matter since these ingredients are disclosed in the specification at page 11, and in several of the disclosed compositions, e.g., Compositions 6, 7, 8, 9, 11, 12, 13, 15, 17, 19, 20, 22, 23, 28 and 30.

Amended claim 1 also reads on the elected species.

Some of the dependent claims, e.g., claims 4, 7 and 10 have also been amended to include jojoba oil and borage oil.

Claim 16 has been amended as in claim 1. Dependent claims 19 and 22 have also been amended to include said compositions.

Similar amendments have also been made in claim 28.

Reconsideration is requested of the rejection of the claims, as now amended. Neither U.S. 6,242,012 B1 (Newmark et al.) nor U.S. Publication No. 2003/0045829 A1 (Gehling et al.) disclose or suggest the unique combination of ingredients claimed herein, which are particularly effective for treatment of vaginal dryness.

Newmark et al. discloses herbal compositions which can promote pre- and postmenopausal hormonal balance in women. The ingredients disclosed by Newmark et al. are, ginger, rosemary, evening primrose oil, olive oil, black

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cohosh, dong quai, achizandra berry, vitex extracts and chaste tree berry. See Abstract, and col. 3, ls. 3-59. See also claim 1.

Newmark et al. does not disclose several ingredients which are disclosed and claimed in the present application, in particular, jojoba oil, borage oil, calendula and aloe vera. Thus Newmark et al. fails to disclose or suggest the combination of the claimed composition defined by applicants' amended claims. Since Newmark et al. does not disclose the combination of ingredients used in applicants' claimed composition, it can not be stated, nor predicted, that the use of ingredients which are not disclosed by this reference is obvious or that it will yield the same efficacious results.

Newmark et al. also fails to disclose the use of antibacterial agents as claimed in several of the dependent claims in the present application. See, e.g., claims 2 and 3.

Quite apart from the aforementioned deficiency of Newmark et al., the declarations of the inventors Harold Mermelstein and Frank Marchese support the superior effectiveness of applicants' composition as compared to the compositions of Newmark et al.

Reconsideration is also requested of the rejection of the claims of the present application over Newmark et al. further in view of (Gehling et al.) and Remington's Pharmaceutical Science (Remington) as set forth in paragraphs 5 and 6 of the Office Action.

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Gehling et al. relates to a tampon adapted to deliver a therapeutic agent. As disclosed at [0052], ls. 7-11, therapeutic and other beneficial agents are delivered to the user's body using tampons. The therapeutic and other agents disclosed are vitamins, hormones, moisturizers, antifungal agents, antibacterial agents, pro-biotic agents that promote the growth of normal vaginal bacteria flora. Several botanicals are disclosed at [0056], ls. 1-6 which include aloe vera, comfrey, calendula, dong quai, black cohosh, chamomile, evening primrose, rosemary and borage seed oil. These botanicals may be combined with vitamins, calcium, magnesium, hormones and analgesics. See [0057], ls. 1-7. There is no disclosure in Gehling et al. which informs one skilled in the art which ingredients should be combined for preparing an effective composition which is suitable for treatment of vaginal dryness. One skilled in the art could not, from the disclosures of Newmark et al. and Gehling et al., select the optimum or most suitable combination of ingredients for preparing a composition as defined by applicants' claims. There is simply no guidance in either reference regarding the selection of the ingredients for preparing such compositions.

Gehling et al.'s disclosure of the use of antibacterial agents is too broad to suggest using methyl paraben, propyl paraben or imidazolidinyl urea as the antibacterial agent. There are simply too many antibacterial agents to focus on and select those which are recited in the present claims.

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Remington's disclosure of propylene glycol as a humectant does not add any meaningful basis to the rejection.

Applicants herein have discovered that a certain, albeit limited combination of ingredients are more effective vaginal moisturizers than the hitherto known or disclosed compositions. As stated in In re Fay and Fox, 146 U.S.P.Q. 47 (CCPA 196), at 50:

The fact that appellants have found a limited class of materials among the necessarily larger number of prior art materials is itself a factor to consider as evidence of unobviousness of the claimed invention. See In re Ruschig, 52 CCPA 1238, 343 F.2d. 965, 145 USPQ 274. (Emphasis in original).

Moreover, as it was stated by the Court of Customs and Patent Appeals in In re Fay and Fox, supra, at 49:

Due to the fact that chemistry is still largely an empirical science it is easy to characterize inventions in the chemical field as but the result of "routine testing". It cannot be denied that "routine testing" is an essential part of many inventions in the chemical field. But even "routine testing", whatever that may be, must be guided and directed by the mental concept of the inventor

Thus, the selection of the most effective combination of ingredients from the vast number of available and known herbal ingredients, and the selection of specific antibacterial agents from the large number of antibacterial agents known in the art, to form the unique combination claimed in the present application is not obvious under 35 U.S.C. 103.

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The annexed Declaration of Harold Mermelstein clearly establishes the superiority of the instantly claimed composition over the Newmark et al. composition above or in combination with Gehling et al. even if the latter patent was available as prior art. The annexed Declaration of Frank Marchese clearly establishes that the inventors of the present invention had conceived and reduced to practice the instantly claimed invention, or at least so much of the composition as it happens to be disclosed by Gehling et al. Thus, under In re Stempel, 113 U.S.P.Q. 77 (CCPA 1957), Gehling et al. is not available as prior art reference against he claims in this application.

In view of the foregoing amendment and remarks, a favorable action is requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'James W. Badie', is written over a horizontal line.

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